



**UNITED STATES DEPARTMENT OF COMMERCE**  
**United States Patent and Trademark Office**

Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
-----------------	-------------	----------------------	---------------------

09/459,712 12/13/99 YURINO

N 07898/053001

020985 HM22/0409  
FISH & RICHARDSON, PC  
4350 LA JOLLA VILLAGE DRIVE  
SUITE 500  
SAN DIEGO CA 92122

EXAMINER

MARSCHER, A.

ART UNIT

PAPER NUMBER

1631

DATE MAILED:

7  
04/09/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trad marks**

# Office Action Summary

Application No.  
**09/459,712**

Applicant(s)

**Yurino et al.**

Examiner

**Ardin Marschel**

Group Art Unit

**1631**



☒ Responsive to communication(s) filed on Jan 17, 2001

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claim

☒ Claim(s) 1-7 is/are pending in the application

Of the above, claim(s) 7 is/are withdrawn from consideration

☐ Claim(s) is/are allowed.

☒ Claim(s) 1-6 is/are rejected.

☐ Claim(s) is/are objected to.

☒ Claims 1-7 are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number)

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received:

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s).

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

Applicants' election of Group I (claims 1-6) in Paper No. 6, filed 1/17/01, is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (M.P.E.P. § 818.03(a)).

Claims 1-6 are rejected, as discussed below, under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The metes and bounds of the sample practice as compared to the claimed method of hybridization detection in the claims are vague and indefinite. If hybridization is meant to be the detected interaction between probe and sample, what is meant by the detection of the amount of a sample that is bound to the probe if the sample is generically cited in the claims. Most nucleic acid containing samples are cellular in nature with only a small portion being nucleic acid. Is the sample in the instant claims already purified so as to only be nucleic acid? Is the sample entirely thus able to bind by hybridization to the probe so as to determine the amount of hybridized sample? If only a small portion of the sample is nucleic acid, what is meant by utilizing hybridization for determining the amount of the sample per se, when the amount of the sample and the amount of the nucleic acid therein is vastly different? Clarification via

clearer claim wording is requested.

Another unclarity in the claims is that line 1 of claim 1, for example, indicates that a "hybridization" method of detection is being claimed. Confusingly, line 3 of claim 1 indicates that the sample is "bound" to the probe. Is this binding "hybridization"? It is noted that binding between various biomolecules is a broader and far more generic term than hybridization. For example, binding may occur via charge difference such as in ionic binding. Binding may occur via a covalent attachment between biomolecules. Therefore, the antecedent basis for "bound" in line 3 of claim 1 is unclear in that it is so much broader than the only possibly related word in the claim given as "hybridization". The unclarity of "bound" versus "hybridization" wording is present in claims 1-6 either directly or via dependence from other claims. Clarification via clearer claim wording is requested.

Claim 2 is additionally vague and indefinite in that line 1 therein indicates detecting the hybridization between probe and a sample whereas confusingly the value determined in lines 2-5 of claim 2 is generated from the "difference" between probe and sample bound to probe which does not seem to be what the claim set out to determine in said line 1. Claim 6 also contains this confusing conflict in what is being determined versus what the claim sets forth in the preamble to determine. Clarification via

clearer claim wording is requested.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1-4 and 6 are rejected under 35 U.S.C. § 102(e) as being anticipated by Walt et al. (P/N 6,023,540).

Walt et al. discloses the preparation and use of fiber optic sensors with microspheres attached on the surface. These microspheres are attached randomly and must be analyzed or decoded as to which microspheres are where on the fiber optic surface as well as detecting the sample or analyte. This is summarized in the section entitled "SUMMARY OF THE INVENTION" in the reference in columns 3-4. The probe practice directed to nucleic acids and hybridization is summarized in column 10, lines 5-41, and Table V. The detection of the amount of analyte in the system of Walt et al. is disclosed in column 11, lines 8-14, as determination of the concentration of analyte which determines the amount inherently in any sample. A Genosensor is disclosed in column 15, lines 16-40, wherein the subpopulations of

microspheres are determined which is a determination of the number and correspondingly the amount of microsphere/probe combinations on the fiber optic bundle surface. Thus, both the probe and sample analyte amounts are determined in Walt et al. as also required in instant claim 1. The normalization of signal caused by the target binding to the microspheres as required in instant claim 2 via a difference in the amount of probe and sample bound to probe is disclosed in column 10, lines 5-17. A change is detected by comparing signals prior to and after sample hybridization as required in instant claim 3. The decoding of the microspheres after analyte binding, as in instant claim 4, is disclosed in column 11, lines 1-14, wherein the decoding of the microsphere is performed after noting which microspheres changed their optical signature. The Figures such as 8A - 10B of Walt et al. display the results as required in instant claim 6.

No claim is allowed.


Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703)308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (703)308-3894. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703)308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Patent Analyst, Tina Plunkett, whose telephone number is (703)305-3524 or to the Technical Center receptionist whose telephone number is (703)308-0196.

April 6, 2001

  
**ARDIN H. MARSCHEL**  
**PRIMARY EXAMINER**